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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,419	02/10/2004	Shubh D. Sharma	056291-5348	2914

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EXAMINER	
SHIBUYA, MARK LANCE	
ART UNIT	PAPER NUMBER
1639	
MAIL DATE	DELIVERY MODE
04/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,419	SHARMA ET AL.	
	Examiner	Art Unit	
	Mark L. Shibuya, Ph.D.	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73-81* is/are pending in the application.

4a) Of the above claim(s) *75 and 77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73,74,76 and 78-81* is/are rejected.

7)☒ Claim(s) *76 and 78-81* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

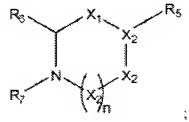
1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/2/04; 10/17/05; 10/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Application 10776419, (20040171520 A1): Claims 73-81 are pending. Claims 75 and 77 are withdrawn from consideration. Claims 73, 74, 76 and 78-81 are examined.

Election/Restrictions

2. Applicant's election of the Invention of



wherein

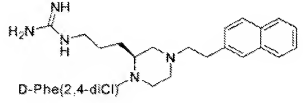
X_1 is CH_2;

X_2, at the 4-position (the position to which R_5 is attached), is N;

X_2, at the 5- and 6- positions, is CH_2; and

n is 1.

and the species of



Example 129

in the reply filed on 1/2/2008, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 75 and 77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/2/2008. The Invention of claims 75 and 77 are taken as drawn to a non-elected Invention, because X_1 is not CH_2, as in the elected Invention.

4. Claims 73, 74, 76 and 78-81 are examined solely to the extent of applicant's elected invention.

Priority

5. This Application 10/776,419, filed 2/10/2004, states that is a continuation of PCT/US02/25575, international filing date 8/12/2002, which claims benefit of US Provisional Application 60/311404, filed 8/10/2001; each incorporated by reference.

Information Disclosure Statement

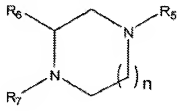
6. The information disclosure statements (IDS) submitted on 8/2/04, 10/17/05 and 10/27/05, were considered by the examiner.

Claim Objections

7. Claims 76 and 78-81 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

In particular, claim 76 is drawn to a molecular core structure as follows:

Claim 76 (new): The peptidomimetic of claim 74 having the formula:

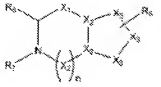


Thus it is apparent that CH_2 at the 5-position has a value of n = 0-3. As such claim 76 encompasses molecules not encompassed within the subject matter of claim 73 and 74, and so claim 76 fails to further limit the claims from which claim 76 depends. Thus claims 76-81 are improper dependent claims.

8. Claims 73-81 are objected to for being drawn to non-elected inventions, because the claims recite inventions not comprising the elected molecular core structure said elected core comprising the limitations wherein X_1 is CH_2; X_2, at the 4-position (the position to which R_5 is attached, is N; X_2, at the 5- and 6- positions, is CH_2; and n is 1.

For example, claim 73 states that X_2 is CH_2, CH, NH or N and wherein n is 0, 1-3.

Furthermore, claim 73 is drawn to a structure:



This structure has a different molecular core ring structure from the elected invention. Because the claims thus lack unity of invention, and given the great number species encompassed by the claims, objection to the claims is proper.

Claim Rejections - 35 USC § 112, First Paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 78-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the

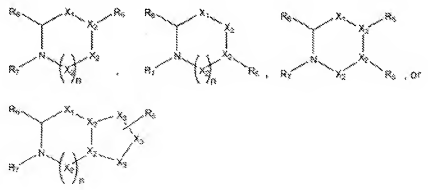
enablement requirement and whether undue experiment is necessitated. These factors can include, but are not limited to:

(1) the breadth of the claims;
(2) the nature of the invention;
(3) the state of the prior art;
(4) the relative skill of those in the art;
(5) the level of predictability in the art;
(6) the amount of direction provided by the inventor;
(7) the existence of working examples; and
(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1 and 2) The breadth of the claims and the nature of the invention: Claims 78-81 are drawn to a method of treating a disease or condition, wherein the disease or condition is an eating disorder, pathologic obesity or sexual dysfunction, comprising administering a peptidomimetic of any one of claims 73-77, and wherein the peptidomimetic is administered as a pharmaceutical composition with a pharmaceutically acceptable carrier; and a pharmaceutical composition comprising the peptidomimetic of any of claim 73-77 and a pharmaceutically acceptable carrier.

Independent Claim 73 is drawn to a peptidomimetic comprising the formula:



wherein X_1 is $(CH_2)_m$ or X_3; X_2 is independently CH_2, CH, NH or N; X_3 is independently $(CH_2)_n$, CH, NH, N, O, C=O, C=S, S, S=O, or SO_2; R_5 is any moiety other than H; R_6 is an amino acid side chain moiety or derivative thereof; R_7 is one or more amino acid residues or derivatives thereof and optionally a terminal group moiety, or is an amino acid side chain moiety or derivative thereof; R_7 and at least one of R_6 or R5 each constitute an element occupying a similar descriptor space as corresponding elements of the biologically active metallopeptide; n is 0, 1, 2 or 3; and m is 0 or 1; provided that any two adjacent CH groups, adjacent NH and CH groups or adjacent NH groups may optionally form a double bond.

Thus the claims encompass a great number of compounds, especially in that the claims are drawn to R groups that can be derivates, i.e., includes any modification to or variation in any amino acid side chain moieties.

(3 and 5) The state of the prior art and the level of predictability in the art: The publication of Jones et al., Current Opinion in Pharmacology, 2003, Vol. 3, pp. 530-543, at p. 530 teaches that the development of peptides as drugs is problematic due to poor oral and tissue absorption, rapid proteolytic cleavage and poor shelf stability. Jones et al., at p. 538, discuss melanocortin-4 agonists and state that development of any MC4R agonist for anti-obesity therapy will depend upon separation of the anorexic effects from spontaneous erectile activity.

(4) The level of one or ordinary skill: The level of skill would be high, most likely at the Ph.D. level. However, such persons of ordinary skill in this art, *given its*

unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have prophetically disclosed the in vivo testing of compounds. The specification does not disclose working embodiments.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The claims contain broad recitations of compounds and state that the claimed invention may be used in methods of treatment and as pharmaceuticals. However, the instant specification does not provide to one skilled in the art those compounds that are active in the whole animal or patient. Applicant's treatment and pharmaceutical claims, which encompass a vast number of compounds, therefore reach through to compounds not yet discovered. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 and n.23, 20 USPQ2d 1438, 1455 and n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure, undue experimentation would be required of one of skill in the art to practice the full scope of the claimed invention.

Claim Rejections - 35 USC § 112, Second Paragraph

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 73, 74, 76 and 78-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 73 recites the terminology "amino acid side chain moiety or derivative thereof" and amino side chain residues or derivatives thereof", which renders the claims vague and indefinite, because one of skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention. The instant specification states:

> The "derivative" of an amino acid side chain moiety includes any modification to or variation in any amino acid side chain moieties, including a modification of naturally occurring amino acid side chain moieties. By way of example, derivatives of amino acid side chain moieties include straight chain or branched, cyclic or noncyclic, substituted or unsubstituted, saturated or unsaturated, alkyl, aryl or aralkyl moieties.

Specification, at p. 19. The examiner respectfully submits that such a derivative that "includes any modification to or variation in any amino acid side chain moieties", encompasses such a universe of chemical structures so as to render the claims vague and indefinite.

Claim 73 recites the limitation "the biologically active metallopeptide". There is insufficient antecedent basis for this limitation in the claim.

The term "similar descriptor space" in claim 73 is a relative term which renders the claim indefinite. The term " similar descriptor space " is not defined by the claim, the

specification does not provide a standard for ascertaining the requisite degree, and one of skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

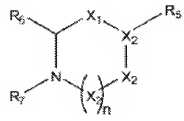
Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 73, 76, and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Sudoh et al., Pharmaceutical Res., vol. 15, no. 5, 1998, pp. 719-725.

The elected invention of the claims is drawn to a peptidomimetic comprising the formula:



;

wherein

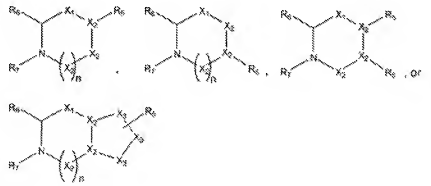
X_1 is CH_2;

X_3, at the 4-position (the position to which R_5 is attached), is N;

X_2, at the 5- and 6- positions, is CH_2; and

n is 1.

The elected invention is to be found within independent Claim 73, which is drawn to a peptidomimetic comprising the formula:

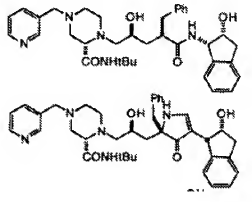


wherein X_1 is $(CH_2)_m$ or X_3; X_2 is independently CH_2, CH, NH or N; X_3 is independently $(CH_2)_n$, CH, NH, N, O, C=O, C=S, S, S=O, or SO_2; R_5 is any moiety other than H; R_6 is an amino acid side chain moiety or derivative thereof; R_7 is one or more amino acid residues or derivatives thereof and optionally a terminal group moiety, or is an amino acid side chain moiety or derivative thereof; R_7 and at least one of R_6 or R5 each

constitute an element occupying a similar descriptor space as corresponding elements of the biologically active metallopeptide; n is 0, 1, 2 or 3; and m is 0 or 1; provided that any two adjacent CH groups, adjacent NH and CH groups or adjacent NH groups may optionally form a double bond.

Claims 73, 76, and 78 are examined solely to the extent of applicant's elected invention and are examined in view of the above rejection under 35 U.S.C. 112, second paragraph.

Sudoh et al., throughout the publication, and at p. 720, Table I, Compounds I and II, teach peptidomimetics that describe the instant Invention. In particular, Sudoh et al. describe the peptidomimetics that are represented by the structures:



Sudoh et al. at p. 720.

Absent evidence to the contrary, the compounds of prior art reference occupy a similar descriptor space as corresponding elements of a biologically active metallopeptide, as the prior art otherwise describes the claimed invention.

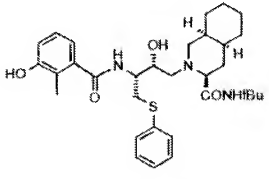
In regard to claim 78, Sudoh et al. teach these compounds as pharmaceutical compounds.

Furthermore, the limitation of claim 78 that the composition be a pharmaceutical, is taken to be an intended use of the peptidomimetics of claims 73 and 76. In that Sudoh et al. teach compounds that meet the limitations of independent 73 and claim 76, the compounds of Sudoh et al. are taken to meet the pharmaceutical limitations of the invention of claim 78.

15. Claims 73, 76, and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Alterman et al., J. Med. Chem., 1998, vol. 41, pp. 3782-3792.

Claims 73, 76, and 78 are examined solely to the extent of applicant's elected invention and are examined in view of the above rejection under 35 U.S.C. 112, second paragraph.

Alterman et al., throughout the publication, and at p. 3783, Figure 1, teach, e.g., a peptidomimetic, Indinavir, that describe the instant Invention. In particular, Alterman et al. describe the peptidomimetics that are represented by the structures:



4

Nelfinavir

Alterman et al., at p. 3783

Absent evidence to the contrary, the compounds of prior art reference occupy a similar descriptor space as corresponding elements of a biologically active metallopeptide, as the prior art otherwise describes the claimed invention.

In regard to claim 78, Alterman et al. teach these compounds as pharmaceutical compounds.

Furthermore, the limitation of claim 78 that the composition be a pharmaceutical, is taken to be an intended use of the peptidomimetics of claims 73 and 76. In that Alterman et al. teach compounds that meet the limitations of independent 73 and claim 76, the compounds of Alterman et al. are taken to meet the pharmaceutical limitations of the invention of claim 78.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 73, 74, and 78-81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 7354923. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '923 Patent is drawn to compounds that encompass the instant elected invention and because the methods of treatment thereof of the instant application would be obvious over the claimed compounds of the '923 Patent, and the claimed pharmaceutically acceptable salts thereof.

Absent evidence to the contrary, the compounds of prior art reference occupy a similar descriptor space as corresponding elements of a biologically active metallopeptide, as the prior art otherwise describes the claimed invention.

18. Claims 73, 74, 76 and 78-81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 14, 18, 19, 20, 22, 23, 24, 26-29 and 31 of copending Application No. 10/837,519. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '519 Application is drawn to compounds that encompass the instant elected invention and methods of treatment thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

19. Claims 73, 74, 76 and 78-81 are rejected. Claims 76-81 are objected to.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya, Ph.D. whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. James Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark L. Shibuya, Ph.D.
Primary Examiner
Art Unit 1639

/Mark L. Shibuya, Ph.D./
Primary Examiner, Art Unit 1639